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09/548,290	04/12/2000	Tatsuya Sasakawa	0018-1098-0	6669

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT PAPER NUMBER

1632

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/548,290

**Applicant(s)**

SASAKAWA ET AL.

**Examiner**

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2004.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29,30 and 32-37 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 29-30, and 32-37 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's response received on 5/28/04 has been entered. Claims 29-30 and 32-37 are pending and under examination in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in previous office actions.

#### ***Claim Rejections - 35 USC § 103***

The rejection of claims 29-30 and 32-36 under 35 U.S.C. 103(a) as being unpatentable over Morita et al. (1999), J. Derm. Science., Vol. 19, 37-43 in view of Yasue et al. (1997) Cell. Immunol., Vol. 181, 30-37, and S.C. Gad (1994) Toxicology, Vol. 93 (1), 33-46, is maintained. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant first argues that none of Morita, Yasue, or Gad teach or suggest the instant invention. The applicant states that Morita et al. teaches the infecting NC mice with live fur mites, not mite extract, that Yasue et al. teaches inhalation of mite extract in mice by aerosol and does not teach sensitization of the ears with mite extract, and that Gad et al. does not suggest using MEST to evaluate the effect of mite extract in mice. In response to applicant's arguments against the references individually, the applicant is

reminded that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The instant rejection is based on the combined teachings of Morita et al. in view of Yasue et al. and Gad et al.

The applicant further argues that despite the fact that Yasue et al. teaches that you can apply mite extract to mice to generate allergic responses, the skilled artisan would not have been motivated to use mite extract since Morita et al. choose to apply live mites rather than mite extract to mice to stimulate atopic dermatitis like symptoms. The applicant argues that since Morita et al. had access to both live mites and to mite extract and only applied live mites, Morita et al. “must have believed that live mites would be more effective compared to mite extract” (Applicant’s response, page 5). In response, Morita et al. states on page 38 that, “The aim of this study was to investigate the role of fur mite infection in the manifestation of skin lesion and the IgE hyper-production in NC” (Morita et al., page 38, column 1, paragraph 1). Since Morita et al. themselves state that the purpose of their experiments was to test the effects of live mite infestation in NC mice, it is not surprising that they choose to use live mites instead of mite extract. There is no indication at all in Morita et al. that live mites are or would be more effective in generating allergic skin responses than mite extract. Morita et al. does not make any such statement. Therefore, applicant’s speculation as to why Morita et al. choose to use live mites base on some expectation that live mites are more effective than mite extract appears to be misplaced and is not supported by the actual teachings in Morita et al.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the rejection of record clearly states that the skilled artisan would be motivated to use a mite extract over live mites in order to standardize the amount of antigen to which each mouse is exposed, thereby ensuring a homogenous population of exposed mice.

The applicant further argues that Yasue et al. does not provide any suggestion or motivation for applying mite extract to the ears since Yasue et al. teaches administration by inhalation and that Gad et al. does not add to the teachings of Morita or Yasue because Gad et al. does not talk about mites or mite extract as an allergen and that the discussion of MEST is general and not directed towards the use of this technique for generating a mouse model for atopic dermatitis. In response, the previous office action acknowledged that neither Morita et al. nor Yasue et al. specifically teach exposing the ears of NC mice to live mites or to mite extract, although it was noted that exposure of NC mice to live mites as taught by Morita et al. may result in live mites on the ears. S. C. Gad was cited to supplement Morita et al. and Yasue et al. by teaching that the application of an allergen or irritant to mouse ears results in an objective and quantifiable response, measured as ear swelling (Gad, page 34, 36, and 40). Gad states that evaluation of allergic responses when animals have been sensitized at sites that do not include the ears is more subjective and

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qualitative and thus less desirable than ear sensitization (Gad, page 40). Thus, Gad provides motivation for sensitizing a mouse with an allergen on the ear as opposed to other locations. Therefore, in view of the teachings provided by Gad that ear sensitization with allergen is more objective and quantifiable than other sites of allergen sensitization, the previous office action concluded that it would have been *prima facie* obvious to the skilled artisan at the time of filing to apply the mite extract taught by Yasue et al. on the ears of the NC mice in the mouse model of atopic dermatitis taught by Morita et al. The applicant's arguments that none of Morita et al., Yasue et al., or Gad specifically suggest applying mite extract to the ears are not compelling because the test for combining references is not what the individual references themselves suggest, but rather what the combination of disclosures taken as a whole would have suggested to one of ordinary skill in the art. *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). For the purpose of combining references, those references need not explicitly suggest combining teachings, much less specific references. *In re Nilssen*, 7 USPQ2d 1500 (Fed. Cir. 1988).

Finally, the applicant argues that the claimed mouse has an important advantage over the mouse described by Morita et al. and has been recognized as an important contribution to the art. In response, the rejection of record is not based solely on the mouse model described by Morita et al., it is based on the teachings of Morita et al. in view of Yasue et al. and Gad. The applicant has not provided that any evidence that following the combined teachings of Morita et al. in view of Yasue et al. and Gad as set forth in the rejection of record would not yield the claimed mouse or that the claimed mouse has any unexpected properties. Regarding the submitted abstracts, the utility of the

claimed mice as a model for atopic dermatitis is not disputed. However, the submitted abstracts which show that the claimed mouse can be used as a model for atopic dermatitis do not overcome the *prima facie* case for obviousness established by the office.

The rejection of claim 37 under 35 U.S.C. 103(a) as being unpatentable over Morita et al. (1999), J. Derm. Science., Vol. 19, 37-43 in view of Yasue et al. (1997) Cell. Immunol., Vol. 181, 30-37, and S.C. Gad (1994) Toxicology, Vol. 93 (1), 33-46 as applied to claims 29-30, and 32-36 above, and further in view of Hiroi et al. (1998) Jpn. J. Pharmacol., Vol. 76, 175-183, is maintained. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

Applicant's arguments regarding the teachings of Morita et al. in view of Yasue et al. and Gad have been addressed in detail above and have not been found persuasive in overcoming the rejection of record.

The applicant further argues that Hiroi et al. does not remedy the deficiencies of Morita et al., Yasue et al. and Gad, and states that screening for therapeutic agents using the scoring system described by Hiroi et al. is less accurate than measuring ear thickness. In response, Hiroi et al. was cited for providing motivation for testing potential therapeutic agents in mouse models of atopic dermatitis. Gad was cited for teaching that the application of allergen material to the ears as opposed to other physical locations causes an objective and quantifiable response, measured as ear swelling (Gad, page 34, 36, and 40). Thus, the skilled artisan reading Gad would clearly be motivated to measure ear swelling when testing potential therapeutics. Therefore, the rejection of record stands.

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No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

**ANNE M. WEHBE' PH.D**  
**PRIMARY EXAMINER**

